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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,046	10/18/1999	HENRY C. LIN, M. D.		2270

7590 03/27/2003

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	25

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/420,046	LIN, M. D., HENRY C.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-138* is/are pending in the application.

4a) Of the above claim(s) *131-136* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-130,137 and 138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicant's Extension of Time, Response to Office Action, and Terminal Disclaimer filed 01/02/03.

Terminal Disclaimer

The terminal disclaimer filed on 01/02/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 5,977,175 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 96, 98-106, 114, 116, 117, and 119-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al. US 4,572,833.

Pedersen teaches controlled release composition comprising multiple-unit of active substance being coated with hydrophobic layer (abstract and column 3). The hydrophobic material can be selected from oils, waxes, fats, including higher fatty acids, and mixtures thereof (column 4). Active substance, dosage forms and coating agent are disclosed in columns 6-8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 96, 98-106, 114, 116, 117, 119-125, 137, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al.

Pedersen is relied upon for the reason stated above. In the case that the applicant can overcome the above 102(b) rejection, it is the examiner's position that it would have been *prima facie* obvious for one of ordinary skill in the art to modify Pedersen's multi-unit controlled release composition with the expectation of at least similar result, since Pedersen teaches the advantageous result in the use of hydrophobic material to control the release rate of active substance throughout the GI tract.

Claims 96, 114, and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al., and Crissinger et al. US 5,411,751.

Pedersen is relied upon for the reasons stated above. Pedersen does not teach the additional of nutrient agent as claimed in claim 118.

Crissinger teaches the use of (C_{16}-C_{22}) fatty acid in food product to reduce GI irritation (abstract). The food product further comprises vitamins and minerals (column 3). Thus, it would have been obvious for one of ordinary skill in the art

to prepare Pedersen's composition using the fatty acid in view of the teaching of Crissinger, because the references teach the advantageous result in the use of fatty acid. The expected result would be controlled release dosage form useful in pharmaceutical and/or food products.

Response to Arguments

Applicant's arguments filed 01/02/03 have been fully considered but they are not persuasive. The examiner maintains the original 102(b) and 103 (a) rejections.

Applicant argues that according to applicant's specification, "active lipid" encompasses "a digested or substantially digested molecule having a structure and function substantially similar to a hydrolyzed end-product of fat digestion, *e.g.* glycerol and fatty acids." However, the "wax-like substances" of Pedersen would not qualify as "active lipid", because at wax-like state, the fatty acids would not be considered fully hydrolyzed or "active". Contrary to the applicant's arguments, it is noted that the features upon which applicant relies on are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The "wax-like substances" of Pedersen

also include higher fatty acids such as myristic, palmitic, stearic, and behenic acids (column 4, lines 7-8), which is also use by applicant's invention as "active lipid" (applicant's attention is called to specification at page 12, 5th paragraph). Accordingly, such language suggests that Pedersen does teach a composition comprises "active-lipid".

Applicant argues that the Examiner has not met the burden of establishing a prima facie case of obviousness, because Pedersen fails to teach or suggest the "active lipid". For the reasons stated above, it would have been obvious for one of ordinary skill in this art to, by routine experimentation select the hydrophobic substances, such as myristic, palmitic, stearic, and behenic acids, taught by Pedersen to obtain the claimed invention. Thus, the Examiner has met the burden of establishing a prima facie case of obviousness, because Pedersen does teach a controlled release composition comprises active lipid as claimed by the applicant.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine Pedersen et al. and Crissinger et al., the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is also noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Crissinger is relied upon solely for the teachings of additional nutrient agent. Crissinger teaches the use of fatty acid in an amount insufficient to damage the intestinal epithelium (columns 1-2).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600